



# UNITED STATES PATENT AND TRADEMARK OFFICE

*[Signature]*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,967	12/26/2001	Shigeru Kamei	087147-0443B	2213
22428 7590 09/14/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER LUKTON, DAVID	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/025,967	KAMEI ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9,10 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,9,10 and 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Pursuant to the directives of the response filed 6/21/07, claim 1 has been amended, and claims 7-8 cancelled.

Claims 1-6, 9, 10 and 17-25 remain pending. Claims 4-10 and 17-25 remain withdrawn from consideration. Claims 1-3 are examined in this Office action.

Applicants' arguments filed 9/29/06 have been considered and found not persuasive.



Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,480,868. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In response, applicants have argued that the rejection be held in abeyance.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the compound (recited in the last four lines of claim 1) is an LH-RH antagonist. However, there is no evidence that this is the case. Certainly, other antagonists of LH-RH are known. But the reality in pharmacology is that one cannot "predict" receptor antagonism or even receptor binding merely by viewing the structure of a compound. Minor changes in structure can result in elimination of activity. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Given the unpredictability of structure/activity relationships, "undue experimentation" would be required of the skilled artisan to use the composition of claim 1 to antagonize LH-RH.

The rejection is maintained.

✦

Claim 1 is objected to. The structural formula is not clearly legible. The examiner can determine applicants' intentions with regard to the structures. However, the persons charged with the task of printing the final document may be unwilling to issue the patent if

the structures are unclear. Accordingly, a notice of allowability will not be issued as long as one or more of the structures is unclear.



Claims 1-3 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites (line 12) that the copolymer must have a molecular weight of 5-25K. Then, in the second-to-last line, the claim recites that the polymer has a weight of 2000-50000. This could be viewed as a contradiction. It may be the case that applicants intend for the 2-50K range to apply only to the N-tetrahydrofuranylcarbonyl-substituted peptide, but if this is intended, it should be made more clear.
- Claim 1 recites (third line from last) the phrase "or its acetate salt". It is unclear, however, whether this phrase refers only to the N-tetrahydrofuranylcarbonyl-substituted peptide or whether it refers to any peptide that is encompassed by the generic formula.



The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section §102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section §102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3 are rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,110,904) in view of Deasy (USP 4,874,612) or Hutchinson (USP 4,789,726).

As indicated previously, Haviv discloses (cols 12-25) various peptides falling within the scope of instant claim 1. Also disclosed (col 27, line 8+) is that the peptide can be combined with a PLA/PLG copolymer. Haviv does not suggest selecting a polydispersity that is somewhere in the range of 1.2-4. Each of the secondary references discloses PLA/PGA copolymers that have the requisite polydispersity. For example, this is disclosed in Deasy at col 2, line 45+. Deasy also discloses (col 2, line 45+) the requisite molecular weight. Hutchinson even goes a step further in arguing (col 2, line 51+; col 3, line 53+) that a polydispersity of about 2 is the most statistically probable distribution of molecular weights. A practitioner of the Haviv invention may or may not see an advantage in a polydispersity of 2, but would recognize that such a composition is most likely to be obtained. (Hutchinson also teaches the requisite molecular weight).

Applicants have argued that, by the amendment of 6/21/07, they have incorporated the limitations of claims 7-8 (the 9/29/06 version) into claim 1. However, this statement is not strictly correct. Claims 7-8, as presented on 9/29/06 not only incorporated the

limitations of claim 1, but also incorporated the limitations of claim 5. Claim 5 in turn, required that the polymer be a mixture of polylactic acid, and another polymer. Thus, it might be true that claims 7-8, as presented on 9/29/06, were novel (or perhaps claims 7-8 were not novel). But even if one accepts the proposition that the 9/29/06 version of claims 7-8 were novel, it does not follow that instant claim 1 (6/21/07 version) is novel. The reason is that claim 1 does not require the limitations of claim 5, and so any novelty that might be imparted by claim 5 is rendered moot.

As it happens, the references over which claims 1-3 were previously rejected (12/22/06) still meet the limitations of the claims (6/21/07 version).

✦

Claims 1-3 are rejected under 35 U.S.C. §103 as being unpatentable over Haviv (USP 5,110,904) in view of Boswell (USP 3,773,919) further in view of either Deasy (USP 4,874,612) or Hutchinson (USP 4,789,726).

The teachings of the references were indicated previously. As noted above, among the references that disclose the requisite molecular weight is Deasy. The rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.



A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

✧

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER